REMARKS

Claims 1-14, 16-19, 23-24, 26-27, 30-37, 39-42, 44-58, 62-63, 66-67 and 69-71 are Allowable

The claimed invention (Claim 1) is drawn to a medical device that includes an imaging element for subcutaneous placement in a tissue mass to identify an area of interest in the tissue mass. The medical device also includes a guide element having a separable portion. Of particular significance, the guide element is connected with the imaging element, such that after the imaging element has been deployed within the tissue mass and a delivery apparatus used to deploy the imaging element has been removed from the tissue mass, (i) the imaging element is connected to the guide element and at least part of the guide element extends exteriorly of the tissue mass to permit the locating of the area of interest, and (ii) the separable portion is adapted to be removed from the tissue mass, such that no part of the guide element extends exteriorly of the tissue mass.

Claim 30 is drawn to subject matter similar to that of Claim 1, except that Claim 30 recites a method for localizing and marking an area of interest in a tissue mass. The method includes providing a medical device comprising an imaging element and a guide element connected to the imaging element. The method also includes inserting the medical device into the tissue mass so that at least part of the guide element extends exteriorly of the tissue mass. Further, the method includes, after the imaging element has been deployed within the tissue mass and a delivery apparatus used to deploy the imaging element has been removed from the tissue mass, removing at least a portion of the guide element so that no portion of the guide element extends exteriorly of the tissue mass.

Claim 69 is also drawn to subject matter similar to that of Claim 1, except that Claim 69 is drawn to a delivery apparatus for the percutaneous placement of a medical device at an area of interest in a tissue mass to facilitate subsequent determination of the area of interest. The delivery apparatus includes an introducer defining a lumen having a proximal end and a distal end defining an expulsion opening. The delivery apparatus also includes a piston having a distal end slidably received within the lumen. When the delivery apparatus is in a ready position, the

distal end of the piston is spaced inwardly from the expulsion opening to form a recess between the distal end of the piston and the expulsion opening. The delivery apparatus also includes a medical device that includes an imaging element positioned in the recess for subcutaneous placement in a tissue mass to identify an area of interest in the tissue mass and a guide element connected to the imaging element and having a separable portion.

When the piston is advanced into the recess, at least the imaging element is expelled through the expulsion opening into the tissue mass. Of particular significance, the imaging element and the guide element are connected, such that after the expulsion opening is withdrawn from the tissue mass, (i) the imaging element while still connected to the guide element is placed within the tissue mass at the area of interest, and at least part of the guide element extends exteriorly of the tissue mass, and (ii) the separable portion is adapted to be separated from the guide element, such that no part of the guide element extends exteriorly of the tissue mass.

The Office has rejected claims 1-14, 16-19, 23-24, 26-27, 30-37, 39-42, 44-58, 62-63, 66-67 and 69-71, at paragraphs 6-7 of the Office Action, under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Application Pub. No. 2005/0165305 ("Foerster"). Applicants respectfully traverse the rejections.

None of the cited references, including Foerster, discloses or suggests the specific combination of Claim 1. For example, Foerster does not disclose or suggest a medical device having a guide element connected to an imaging element, such that after the imaging element has been deployed within the tissue mass and a delivery apparatus used to deploy the imaging element has been removed from the tissue mass, (i) the imaging element is connected to the guide element and at least part of the guide element extends exteriorly of the tissue mass to permit the locating of the area of interest, and (ii) the separable portion is adapted to be removed from the tissue mass, such that no part of the guide element extends exteriorly of the tissue mass, as recited in Claim 1. In contrast to Claim 1, Foerster discloses a center wire running through a lumen, where the wire is used as a deployment mechanism for a marker. (Foerster, para. [0054]). Increasing tension applied to a pull ring causes the wire to fail at a point of weakness, thereby releasing the marker into the target tissue. (Foerster, para. [0055]). The center wire disclosed by

Foerster is not connected with the marker, and does not extend exterior to the tissue mass, after the marker is deployed and the delivery apparatus is removed. Hence, Claim 1 is allowable.

None of the cited references, including Foerster, discloses or suggests the specific combination of Claim 30. For example, Foerster does not disclose or suggest a method that includes inserting a medical device into the tissue mass so that at least part of a guide element extends exteriorly of the tissue mass and, after an imaging element has been deployed within a tissue mass and a delivery apparatus used to deploy the imaging element has been removed from the tissue mass, removing at least a portion of the guide element so that no portion of the guide element extends exteriorly of the tissue mass, as recited in Claim 30. In contrast to Claim 30, Foerster discloses a center wire running through a lumen, where the wire is used as a deployment mechanism for a marker. (Foerster, para. [0054]). Increasing tension applied to a pull ring causes the wire to fail at a point of weakness, thereby releasing the marker into the target tissue. (Foerster, para. [0055]). The center wire disclosed by Foerster is not connected with the marker, and does not extend exterior to the tissue mass, after the marker is deployed and the delivery apparatus is removed. Hence, Claim 30 is allowable.

Further, none of the cited references, including Foerster, discloses or suggests the specific combination of Claim 69. For example, Foerster does not disclose or suggest a delivery apparatus that includes a medical device having a guide element connected to an imaging element, where the imaging element and the guide element are connected, such that after the expulsion opening is withdrawn from the tissue mass, (i) the imaging element while still connected to the guide element is placed within the tissue mass at the area of interest, and at least part of the guide element extends exteriorly of the tissue mass, and (ii) the separable portion is adapted to be separated from the guide element, such that no part of the guide element extends exteriorly of the tissue mass, as recited in Claim 69. In contrast to Claim 69, Foerster discloses a center wire running through a lumen, where the wire is used as a deployment mechanism for a marker. (Foerster, para. [0054]). Increasing tension applied to a pull ring causes the wire to fail at a point of weakness, thereby releasing the marker into the target tissue. (Foerster, para. [0055]). The center wire disclosed by Foerster is not connected with the marker, and does not extend exterior to the tissue mass, after the marker is deployed and the delivery apparatus is removed. Hence, Claim 69 is allowable.

CONCLUSION

Applicants have indicated aspects of the claims that are not disclosed or suggested by the references. Applicants submit that the dependent claims are allowable at least by virtue of their dependencies from the independent claims, which Applicants have shown to be allowable. Applicants respectfully submit that the present application is now in condition for allowance. Accordingly, the Examiner is requested to reconsider the application and issue a Notice of Allowance for all pending claims.

Should the Examiner deem that any further action by the Applicants would be desirable for placing this application in even better condition for issue, the Examiner is requested to telephone Applicants' undersigned representative at the number listed below.

The Commissioner is hereby authorized to charge any fees that may be required, or credit any overpayment, to Deposit Account Number 50-3797.

Respectfully submitted,

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Date

Chad M. Herring
Chad M. Herring, Reg. No. 41,067
Attorney for Applicant(s)
LARSON NEWMAN ABEL
POLANSKY & WHITE, LLP
5914 West Courtyard Drive, Suite 200
Austin, TX 78730
(512) 439-7100 (phone)
(512) 439-7199 (fax)